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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/827,384	04/19/2004	Rajiv Doshi	SPIRTN.013C1	3135
20995	7590	01/12/2005	EXAMINER	
KNOBBE MARTENS OLSON & BEAR LLP			PATEL, MITAL B	
2040 MAIN STREET			ART UNIT	
FOURTEENTH FLOOR			PAPER NUMBER	
IRVINE, CA 92614			3743	

DATE MAILED: 01/12/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/827,384

Applicant(s)

DOSHI, RAJIV

Examiner

Mital B. Patel

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 April 2004.
- 2a) ☐ This action is FINAL. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 April 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Oath/Declaration

1. The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:
Non-initialed and/or non-dated alterations have been made to the oath or declaration. See 37 CFR 1.52(c).

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1-4, 6, and 10-15 are rejected under 35 U.S.C. 102(b) as being anticipated by Coe et al (US 5059208).
4. **As to claim 1**, Coe teaches a device for partially occluding an expiratory airway in a patient, the device comprising a frame **14** implantable within a trachea or bronchial passage; and means **36** on the frame for increasing air flow resistance to expiration.
5. **As to claim 2**, Coe teaches a device wherein the means selectively increases air flow resistance to expiration while increasing resistance to inspiration to a lesser extent.

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6. **As to claim 3**, Coe teaches a device wherein the means comprises a flow responsive element which opens to inspiration and closes to expiration.

7. **As to claim 4**, Coe teaches a device wherein the means comprises a fixed element **40**.

8. **As to claim 6**, Coe teaches a method for treating patients suffering from chronic obstructive pulmonary disease, the method comprising creating a resistance to in a tracheal or bronchial passage to expiratory air flow (**See Col. 2, lines 27-49**).

9. **As to claim 10**, Coe teaches a device that partially occludes an expiratory airway in a patient, the device including an air flow resistance element **36** implantable within one of the trachea and a bronchi of the patient.

10. **As to claim 11**, Coe teaches a device wherein the flow resistance element provides a first flow resistance to inspiration and a second flow resistance to expiration, the second flow resistance being greater than the first flow resistance.

11. **As to claim 12**, Coe teaches a device wherein the air flow resistance element comprises a valve **36**.

12. **As to claim 13**, Coe teaches a device further including a frame **14** that supports the valve.

13. **As to claim 14**, Coe teaches a device wherein the flow resistance element provides a first flow resistance to airflow from proximal airways to distal airways, a second flow resistance to first air flow from distal airways to proximal airways, and a third flow resistance to second air flow from distal airways to proximal airways, wherein the second flow resistance is greater than the third flow resistance and the second

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airflow from distal airways to proximal airways is greater than the first airflow from the distal airways to proximal airways.

14. **As to claim 15**, Coe teaches a device wherein the third flow resistance is greater than the first flow resistance.

15. Claim 5 is rejected under 35 U.S.C. 102(b) as being anticipated by McKenna (US 5255687).

16. **As to claim 5**, McKenna teaches a device for enhancing breathing in a patient suffering from chronic obstructive pulmonary disease, the device comprising a mouthpiece **12** for holding in the patient's mouth; and means **26A** on the mouthpiece for increasing flow resistance to expiration while permitting inspiration with reduced resistance.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

17. Claims 6, 7, and 9 are rejected under 35 U.S.C. 102(e) as being anticipated by Alferness et al (US 6258100).

18. **As to claim 6**, Alferness teaches a method for treating patient suffering from chronic obstructive pulmonary disease, the method comprising implantably creating a resistance in a tracheal or bronchial passage to a portion of expiratory air flow. Please note that by implanting device **90,110** in the bronchial passageway resistance to a portion of expiratory flow is created.

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19. **As to claim 7**, Alferness teaches a method wherein the step of creating includes the step of implanting a flow resistor in the trachea or bronchial passage. Please note that the one-way valve of device **90,110** serves as a flow resistor.

20. **As to claim 9**, Alferness teaches a method wherein the step of creating includes the step of applying energy to a portion of the trachea or bronchial passage to partially occlude the lumen of passage. Again, please note that by placing device **90,110** in the bronchial passageway energy is applied to that passageway and there is partial occlusion of the lumen of that passageway.

Double Patenting

21. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

22. Claims 1-15 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-6 and 8-15 of U.S. Patent No. 6,722,360. Although the conflicting claims are not identical, they are not patentably distinct from each other because Applicant has received a patent for a species or more

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specific embodiment and is not entitled to a patent for the generic or broader invention.

The patented claim "anticipates" the application claim. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993).

23. **Claim 1 of the application recites**, "A device for partially occluding an expiratory airway in a patient, the device comprising:" (**See lines 1-2 of claim 1 of patent**) "a frame implantable within a trachea or bronchial passage; and means on the frame for increasing flow resistance to expiration" (**See lines 3-11 of claim 1 of patent**). The difference between claim 1 of the application and claim 1 of the patent lies in the fact that the patent claim includes additional elements/features and is thus more specific. Therefore, the invention of claim 1 is in effect a "species" of the "generic" invention of claim 1 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 1 of the application is anticipated by claim 1 of the patent, it is not patentably distinct from claim 1 of the patent.

24. **As to claim 2 of the application**, the limitations can be found in claim 2 of the patent.

25. **As to claim 3 of the application**, the limitations can be found in claim 3 of the patent.

26. **As to claim 4 of the application**, the limitations can be found in claim 4 of the application.

27. **Claim 5 of the application recites**, "A for enhancing breathing in a patient suffering from chronic obstructive pulmonary disease, the device comprising:" (**See**

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lines 1-3 of claim 5 of patent) “a mouthpiece for holding in the patient’s mouth” (**See line 4 of claim 5 of patent**); “and means on the mouthpiece for increasing flow resistance to expiration while permitting inspiration with reduced resistance.” (**See lines 4-8 of claim 5 of patent**). The difference between claim 5 of the application and claim 5 of the patent lies in the fact that the patent claim includes additional elements/features and is thus more specific. Therefore, the invention of claim 5 is in effect a “species” of the “generic” invention of claim 5 of the application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 5 of the application is anticipated by claim 5 of the patent, it is not patentably distinct from claim 5 of the patent.

28. **Claim 6 of the application recites**, “A method for treating patients suffering from chronic obstructive pulmonary disease, the method comprising:” (**See lines 1-2 of claim 6 of patent and lines 1-2 of claim 8 of patent**) “creating a resistance to expiratory flow in a tracheal or bronchial passage.” (**See lines 3-10 of claim 6 of patent and lines 3-5 of claim 8 of patent**) The difference between claim 6 of the application and claims 6 and 8 of the patent lies in the fact that the patent claims include additional elements/features and is thus more specific. Therefore, the invention of claims 6 and 8 is in effect a “species” of the “generic” invention of claim 6 of the application. It has been held that the generic invention is “anticipated” by the “species”. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 6 of the application is anticipated by claims 6 and 8 of the patent, it is not patentably distinct from claims 6 and 8 of the patent.

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29. **As to claim 7 of the application**, the limitations can be found in claims 6 and 8 of the patent.

30. **As to claim 8 of the application**, the limitations can be found in claim 8 of the patent.

31. **As to claim 9 of the application**, the limitations can be found in claim 9 of the patent.

32. **Claim 10 of the application recites**, "A device that partially occludes an expiratory airway in a patient, the device including a flow resistance element implantable within one of the trachea and a bronchi of the patient (**See claim 10 of patent**). The difference between claim 10 of the application and claim 10 of the patent lies in the fact that the patent claim includes additional elements/features and is thus more specific. Therefore, the invention of claim 10 is in effect a "species" of the "generic" invention of claim 10 of the application. It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claim 10 of the application is anticipated by claim 10 of the patent, it is not patentably distinct from claim 10 of the patent.

33. **As to claim 11 of the application**, the limitations can be found in claim 11 of the patent.

34. **As to claim 12 of the application**, the limitations can be found in claim 12 of the patent.

35. **As to claim 13 of the application**, the limitations can be found in claim 13 of the patent.

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36. **As to claim 14 of the application**, the limitations can be found in claim 14 of the patent.

37. **As to claim 15 of the application**, the limitations can be found in claim 15 of the patent.

Conclusion


38. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 6083141, US 5391205, US 5383470, US 5038621, US 5033312, US 4533137, US 4456016, and US 4403616.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Mital B. Patel whose telephone number is 571-272-4802. The examiner can normally be reached on Monday-Friday (11:00-7:30).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on 571-272-4791. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Mital B. Patel
Examiner
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1/6/05